EPA REGISTRATION NUMBER 1448-442

PROCESSING REQUEST

Reg # 1448-442 **Decision #**

Description:

Material Available Electronically (see PPLS):

☑ Electronic Label/Letter Dated

☐ Other:

Material Sent (see jacket):

☐ Stamped Label/Letter Dated

☐ Notification Dated

☐ New CSF(s) Dated

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: D Copeland

Division:

Phone: **Date:** 7/9/15

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
X Registration
___ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
1448-442	7/9/15

Term of Issuance:
Unconditional

Name of Pesticide Product:
BUSAN 1474

Name and Address of Registrant (include ZIP Code):
Buckman Laboratories, Inc.
1256 N. McLean Blvd.
Memphis, TN 38108

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:	Date:
John Hebert, Branch Chief RMB1 Antimicrobials Division (7510P)	7/9/15

EPA Form 8570-6

2. Make the following label changes before you release the product for shipment:

- Revise the EPA Registration Number to read, "EPA Reg. No. 1448-442."

3. Submit one copy of the revised final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated June 11, 2015

If you have any questions, please contact John Hebert by phone at 703-6249 by phone at 703-308-6249, or via email at hebert.john@epa.gov.

Sincerely,

John Hebert, Chief
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Stamped label

BUSAN® 1474

Buckman

A microbicide used to help control algae, bacteria, fungi, archaea and other micro-organisms in makeup, recycled, flowback, injection, and produced fluids and waters associated with oil and gas production (i.e., drilling, stimulation, hydraulic fracturing, production, and disposal operations).

ACTIVE INGREDIENT:	
Ammonia (Total)	7.59%
INERT INGREDIENTS:	92.41%
TOTAL	100.00%

ACCEPTED
07/09/2015
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 1448-442

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID	
IF SWALLOWED	• Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything to an unconscious person.
IF INHALED	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
IF IN EYES	• Hold eye open and rinse slowly and gently with water for 15–20 min. • Remove contact lenses, if present, after first 5 min. then continue rinsing eye. • Call a poison control center or doctor for further treatment advice.
IF ON SKIN, CLOTHING	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15–20 min. • Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment. You may also contact 901-767-2722 for emergency medical treatment information.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed. Avoid breathing vapor. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS: The pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

OIL AND GAS SYSTEMS: This product is used to help control algae, bacteria, fungi, archaea and other micro-organisms in waters and fluids associated with oil and gas production.

This product is applied in conjunction with sodium hypochlorite to form monochloramine, an oxidizing microbiocide. The products are added to dilution water to achieve a minimum molar ratio of 1.0 to 1.0, this product to sodium hypochlorite. This ratio may be obtained by combining 0.5 fluid ounces of this product to 1.0 fluid ounces of sodium hypochlorite (less than or equal to 15.0% wt/wt). To ensure both handling safety and effectiveness, the monochloramine solution must be generated and fed into the treatment water process through a closed metered chemical feed system. The system operator must be trained by a Buckman representative in the use of the chemical feed system. Use of this product for any other purposes or contrary to the use directions specified below is prohibited.

Dosage Rates: Apply sufficient product and sodium hypochlorite to achieve a total chlorine residual of at least 1 ppm in excess of the system oxidant demand. Once this residual concentration is achieved, treatment rates may be reduced to sub-demand rates from 50% to 80% of system demand.

The product may be added to the system continuously or intermittently as needed to any area of the system where uniform mixing can be obtained.

For intermittent treatment, mix 0.5 fluid ounces of this product to 1.0 fluid ounce of sodium hypochlorite (less than or equal to 15.0% wt/wt). Apply the solution at a rate to obtain 1 to 2 ppm in excess of the system oxidant demand (maximum of 4 ppm measured) as total chlorine in the water being treated for 5 to 60 minutes every 1 to 6 hours. The frequency of feeding and the duration of treatment will depend on the severity of the problem.

For continuous treatment, mix 0.5 fluid ounces of this product to 1.0 fluid ounce of sodium hypochlorite (less than or equal to 15.0% wt/wt). Apply the solution at a rate to obtain 0.5 to 1 ppm in excess of the system oxidant demand (maximum of 4 ppm measured) as total chlorine in the water being treated on a continuous basis. The frequency of feeding and the duration of treatment will depend on the severity of the problem.

Chloramine levels must be monitored. If chloramine is detected in the effluent or in water targeted for disposal into surface waters, it must be neutralized to levels below 2 ppb for freshwater and 3 ppb for saltwater by the addition of sodium metabisulfite.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Keep container tightly closed. Store in a dry place. Leaking or damaged drums should be placed in overpack drums for disposal. Spills should be absorbed in sawdust or sand and disposed of in a sanitary landfill. Keep container closed when not in use.

PESTICIDE DISPOSAL: Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or Hazardous Waste representative at the nearest EPA Regional office for guidance. Clean equipment and/or dispose of equipment wash water in a manner to avoid contamination of water resources.

CONTAINER HANDLING: NONREFILLABLE CONTAINER. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container (or equivalent) promptly after emptying.

(capacity of 5 gallons or less) Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for the later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

(capacity of greater than 5 gallons) Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use of disposal. Repeat this procedure two more times.

(all) Then offer for recycling if available or reconditioning, if appropriate, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities by burning. If burned, stay out of smoke. If metal container, do not puncture or burn.

CONTAINER HANDLING: REFILLABLE CONTAINER. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.

(capacity of greater than 55 gallons) To clean the container prior to refilling or disposal, use a pressure wash as follows: Empty the remaining contents into application equipment or a mix tank. Use a pressure wash system that rinses all interior sides with water and that is rated at >40 psi and >120°F. Pressure wash the container for a length of time that ensures that a minimum 25% of the container volume of water is used. During the pressure wash, ensure that the container valve is left open for continuous draining. Collect the rinsate and empty into application equipment or a mix tank or store rinsate for later use or disposal. Allow container to drain for 10 minutes after pressure wash is completed.

(capacity of 55 gallons or less) To clean the container prior to refilling or disposal, use a triple rinse wash as follows: Empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously. Pour or pump rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this rinsing procedure two more times.

Manufactured by:

Buckman Laboratories, Inc.
1256 N. McLean Blvd., Memphis, Tennessee 38108, U.S.A.
(901) 278-0330 or 1-800-282-5626

☐ **EPA Est. No. 1448-TN-1** ☐ **EPA Est. No. 1448-MO-1**
EPA Reg. No. 1448-XYZ

Product Weight: 9.59 lbs/gal 1.15 kg/L
NET CONTENTS MARKED ON CONTAINER

HMIS/NPCA RATING
Health 1 Flammability 1 Reactivity 0

Revised: 07/07/15

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 26, 2015

Mr. Carl Watson, PH.D.
Buckman Laboratories, Inc.
1256 N. McLean Blvd
Memphis, TN 38108

SUBJECT: EPA Registration Symbol: 1448-UUE
Applications Dated: September 30, 2014
Receipt Dates: October 1, 2014

Dear Mr. Watson:

Our records indicate that the decision review period for EPA to make a determination regarding the above referenced application ends on July 29, 2015 as pursuant to the Pesticide Registration Improvement Act (PRIA). The application has been determined, pursuant to 40 CFR 152.105, not to be sufficiently complete to process; therefore, the application is considered deficient. Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

Pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it.

Address the following deficiencies for:

1. Product Chemistry Review (dated June 23, 2015)
2. Risk Assessment Science Support Branch Review dated (May 6, 2015)

FIFRA Section 33/PRIA:

This application is also subject to a deadline for making a determination on the application under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA. The time frame for the Agency to make a determination on this application ends of July 29, 2015. Because the deadline for the agency to make a determination on this application expires before the end of the 75 days you have to respond to the deficiencies noted above, you have the following three options:

1. Withdraw the application. Alternatively, you may notify us not later that July 7, 2015 that you are withdrawing your application. As noted above, withdrawal concludes the Agency's review of your application; however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service fee.

2. Not respond. If the Agency does not hear from you July 7, 2015, the Agency in meeting its obligations under section 33/PRIA may issue a determination to not grant your application. While a determination to not grant an application would allow EPA to have met its obligation under section 33 of FIFRA to issue a determination by a specified date, this determination is neither a denial of the application pursuant to section 3(c)(6) of FIFRA or a withdrawal of the application. Thus, the Agency will continue to diligently work on any such application as long as EPA receives a response to a deficiency notice within the 75 days described above.

Please respond to this letter by July7, 2015, by contacting Drusilla Copeland by telephone, (703) 308-6224, or by e-mail at copeland.drusilla@epa.gov or John Hebert by telephone at (703) 308-6249 or by e-mail at hebert.john@epa.gov with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Drusilla Copeland for

Velma Noble
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Attachment: Product Chemistry Review dated 5/6/2015 and Risk Assessment Science Support Branch Review 6/23/2015

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

June 23, 2015

EPA Reg#: 1448-UUE			DP Barcode: 423831	
			Submission #: 958589	
Product name: Busan 1474			Registrant: Buckman Laboratories, Inc.	
Reviewer's name: Juan F. Negrón			AD/PSB/CTT- Product Chemistry Reviewer	
Agency due date: 07/29/15			PSB received date: 11/14/2014	
CTT received date: 11/17/2014			Science received date: 11/18/2014	
Formulation type: EUP			Pesticide classification: Disinfectant	
Integrated system: []		Non-integrated system: [x]	Food use: []	Non food use: [x]
Action Code: A480		Date Completed: 06/09/2015		
PC Code(s)	CAS #(s)	Active Ingredient Names		% wt (label)
005302	7664-41-7	Ammonium		7.59
Molecule structure (optional):				
Comments:				
Approver: Karen P. Hicks			Approved date: 06/23/2015	

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

June 23, 2015

MEMORANDUM

Subject: Product Chemistry Review for EPA Reg # 1448-UUE
Product Name: Busan 1474
DP Barcode: 423831

From: Juan F. Negrón, Chemist
Product Science Branch, CT Team
Antimicrobials Division (7510P)

Thru: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510P)

To: Velma Noble / Drusilla Copeland
PM Team 31

APPLICANT: Buckman Laboratories, Inc.
Action code: A480
Due date: 07/29/15

Product Formulation
Active Ingredient from label:

	% by wt.
Ammonium	7.59

BACKGROUND:

The registrant, Buckman Laboratories, Inc., is submitting an application for an end-use product, "Busan 1474" as an-integrated system non-food use. The registrant submitted a me-too, EPA Reg # 3008-89, application. The Product Chemistry Reviewer has reviewed the following documents:

- Confidential Statements of Formula (CSFs), dated 10/08/2014, & 06/11/2015, for the basic formulation, & an alternate formulations.
- A draft label, pin punched on 10/11/2014.
- A letter, undated (see e-suh # 7204).
- Transmittal document, dated 01/28/2015, MRID # 49394400.
- Application for pesticide registration, dated 01/21/2015.
- Formulator's Exemption Statement, dated 01/14/2015.
- Certification with respect to citation of data, dated 01/23/2015.
- Summary of the Physical/Chemical properties, dated 07/2014.
- Data matrix, dated 01/28/2015.
- A study titled "Product Chemistry for BUSAN 1215 Product Identity, Composition and Analysis" dated 12/21/2004, MRID # 46435102.
- A study titled "Product Chemistry for BUSAN 1215 Physical I Chemical Properties" dated 12/20/2004, MRID # 46470002.
- A study titled "Storage Stability and Corrosion Characteristics" dated 06/30/2005 MRID # 46586501.

FINDINGS:

1. The CSFs, dated 10/08/2014, for the basic formulation, & an alternate formulation are obsolete. The CSFs consisted of: The basic formulation (one page) and an alternate formulation that consisted of two pages. The alternate formulation is a pre-reaction.

2. The CSF, dated 06/11/2015, for the basic formulation is revised.

3. The CSF and the label have the same nominal concentration for the active ingredient (AI).

4. The product is a re-pack from the EPA Reg # 1448-432, BCMW. The nominal concentration as per label shows 7.59% for the active ingredient (AI). The nominal concentration for the proposed new product is also 7.59% as per label for the AI.

5. Since the me-too product, EPA Reg # 1448-432, BCMW, is from the same proposed new product company, the 830 Groups (A & B) have been cited using the MRID #s shown in table below.

6. The storage stability and corrosion characteristic studies are waived since it is a me-too application. Nevertheless, the registrant provided the study that included the storage stability and corrosion characteristic.

7. The pre-reaction shows certified limits.

8. The registrant conducted a storage stability and corrosion characteristic study, and the results are as follows:

Study titled "Storage Stability and Corrosion Characteristics" dated 06/30/2005 MRID # 46586501.			
Replicate #	% Nitrogen	%Ammonia	% Average
Initial time period (% ± 0.03)			
6	6.25	7.58	7.6
7	6.25	7.58	
8	6.29	7.63	
3 Month (% ± 0.03)			
1	6.26	7.60	7.6
2	6.30	7.65	
3	6.29	7.63	
6 Month (% ± 0.04)			
1	6.14	7.45	7.5
2	6.19	7.51	
9 Month (% ± 0.02)			
1	6.17	7.49	7.5
2	6.20	7.52	
12 Month (% ± 0.04)			
1	6.23	7.56	7.5
2	6.18	7.50	
Meets the EPA Standard Certified Limits. Corrosion Characteristic guideline: No physical changes were observed over the test period.			

A storage stability test was carried out in an opaque High Density Polyethylene (HOPE) container. Four sub-samples of the test substance were put into storage for one year following initial characterization of the active. Percent active ingredient was determined using distillation and titration. One sample was analyzed for the active ingredient at 0, 3, 6, 9, and 12 months. Linear regression, precision and accuracy were performed to ensure method performance. At initiation and at the end of each storage phase, the physical appearance of the product and container was observed and recorded. The test substance was in contact with the container throughout the storage period.

9. The 830 Groups (A & B) guidelines have been met.

CONCLUSIONS:

The CSF, dated 06/11/2015, for the basic formulation is acceptable and superseded previous CSFs. The registrant is not changing the proposed new product formulation. The 830 Groups (A & B) guidelines have been met.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system []
- Are all TGAIs used registered? Yes [x] No []
- Integrated formulation system [x]
- If "ME-TOO," specify EPA Reg. No. of existing product: 3008-89

b. Clearance of inerts for non-food:

Yes [x] No []

c. Physical state of product: Liquid

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes [] No [X]

e. The NCs and CLs are acceptable. Yes [X] No []

f. Active ingredients	NC (%)	LCL (%)	UCL (%)
Ammonium	7.59	7.21	7.97

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [X]
- Have all impurities of ≥ 0.1% in the product been identified?
  Yes [ ] No [ ] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X] No []

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.
Yes [ ] No [ ] Not applicable [X]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.
Yes [] No []

f. The product requires an expiration date at which time the NC falls below the LCL
Yes [] No []

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity	A This came from the product, Busan 1215. See data matrix, dated 09/29/2014 (repack)	46435102
830.1600 Description of Materials	A This came from the product, Busan 1215. See data matrix, dated 09/29/2014 (repack)	46435102
830.1620 Production Process	*[Not required for end -use products.]*	
830.1650 Formulation Process	A This came from the product, Busan 1215. See data matrix, dated 09/29/2014 (repack)	46435102
830.1670 Formation of Impurities	*[Not required for end -use products.]*	
830.1700 Preliminary Analysis	*[Not required for end -use products.]*	
830.1750 Certified Limits	A This came from the product, Busan 1215. See data matrix, dated 09/29/2014 (repack)	46435102
830.1800 Enforcement Analytical Method	A "Free Ammonia and Ammonium Ion by Distillation and Titration." This came from the product, Busan 1215. See data matrix, dated 09/29/2014 (repack)	46435102
830.1900 Submittal of Samples	Available upon request.	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable; NR= not required; G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	A	*[Not required for end -use products.]* However the study reveals that the test substance is clear, colorless. This came from the product, Busan 1215. See data matrix, dated 09/29/2014 (repack)	46470002
830.6303 Physical State	A	Liquid This came from the product, Busan 1215. See data matrix, dated 09/29/2014 (repack)	46470002
830.6304 Odor	NR	*[Not required for end -use products.]* However, the study reveals that the odor is ammoniacal. This came from the product, Busan 1215. See data matrix, dated 09/29/2014 (repack)	46470002
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NR	*[Not required for end -use products.]* However, the registrant has indicated that the product is stable @ 50 °C for 28 days.	46470002

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6314 Oxidation/ Reduction: Chemical Incompatibility	A	Weak oxidizer/reducer. The aqueous ammonia [NH3(aq)], ammonium ion (NH/), and sulfate ion (S04 –) that comprise BCMW all have very weak oxidizing or reducing properties. Neither aqueous ammonia nor ammonium ion can be further Buckman Laboratories International, Inc. BUSAN 1215, Series 63 8 reduced. Aqueous ammonia can be attacked by strong oxidizing agents, as demonstrated by its conversion to nitrogen gas by excess sodium hypochlorite. However, it is not easily oxidized, as suggested by its relatively low oxidation potential: 2NH3(aq) ~ N2(g) + 6H+ + 6e· E0 o, = +0.092 v vs. NHE Higher, more positive oxidation potentials would indicate that a substance is more readily oxidized; or, in other words, it would be a stronger reducing agent. For example, compare the oxidation potential shown above with that of a substance known to be a strong reducing agent (sulfite ion in alkaline solution): so,~+ 20ff ~so.~+ 2e· + H,o E0 0 , = +0.936 V vs. NHE Hence, ammonia would be considered to be a weak reducing agent at best.	46470002
830.6315 Flammability/ Flame Extension	A	>200° F (closed cup).	46470002
830.6316 Explodability	A	Not applicable, inorganic salt solution.	46470002
830.6317 Storage Stability	A	See finding #6.	46586501
830.6319 Miscibility	A	This product is a dilute aqueous ammonia solution formed from water dilution of ammonium sulfate. As an aqueous solution it is miscible in water.	46470002
830.6320 Corrosion Characteristics	A	Corrosive to yellow metals such as bronze. Not recommended containers made from Acetal, natural rubber, polycarbonate, polyurethane and viton. Softening, loss of strength, swelling may occur in materials made of LDPE. Minor effects on PVC. See finding #6.	46470002, 46586501

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6321 Dielectric Breakdown Voltage	A	Not applicable. This product is an inorganic salt solution, not intended for use around electrical equipment.	46470002
830.7000 pH	A	9.26 ± 0.3 @ 25 °C	46470002
830.7050 UV/Visible Absorption	NR	*[Not required for end -use products.]*	
830.7100 Viscosity	A	3.5 ± 0.1 cps at 25 °C Method - The product viscosity was determined with a Brookfield viscometer using a spindle #1 at 60 rpm, sample temp 25°C.	46470002
830.7200 Melting Point/Melting Range	NR	*[Not required for manufacturing -use products.]*	
830.7220 Boiling Point/Boiling Range	NR	*[Not required for end -use products.]* However it has been reported as 100.3 °C	46470002
830.7300 Density/Relative Density/Bulk Density	A	1.15 g/cm^3 at 25 °C	46470002
830.7370 Dissociation Constants in Water	NR	*[Not required for end -use products.]* (ammonia) Pka 9.25 at 25 °C.	46470002
830.7520 Particle Size	NR	*[Not required for end -use products.]*	
830.7550/830.7560/ 830.7570 Partition Coefficient	NR	*[Not required for end -use products.]*	
830.7840/830.7860 Water Solubility	NR	*[Not required for end -use products.]*	
830.7950 Vapor Pressure	NR	*[Not required for end -use products.]*	

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; NR= not required; G=data gap.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

February 4, 2015

MEMORANDUM

SUBJECT: Acute Toxicity Review for EPA Reg. No.: 1448-UUE
DP Barcode: D423833

FROM: Chris Jiang, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Chris Jiang
2/4/15

THRU: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Seience Branch
Antimicrobials Division (7510P)

TO: Velma Noble PM 31/Drusilla Copeland
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Buckman Laboratories Inc.

FORMULATION FROM LABEL:

Active Ingredient(s):	
Ammonia (total)	7.59 %
Inert Ingredient(s):	92.41 %
Total:	100.00 %

BACKGROUND: The registrant has submitted an acute toxicity package for the registration of this non-integrated end-use product. The package includes a cover letter, a label that is pinpunched 10/1/14, a Confidential Statement of Formula (CSF) for the basic formulation, and a review for 1448-432 (1448-UGE) done under D313223.

FINDINGS:

1. The current acute toxicity profile for EPA Registration No. 1448-UUE is:

Study	MRID Number	Toxicity Category	Status
Acute Oral Toxicity	46435108	IV	Cited
Acute Dermal Toxicity	46435109	IV	Cited
Acute Inhalation Toxicity	46435110	IV	Cited
Acute Eye Irritation	46435110	IV	Cited
Acute Dermal Irritation	46435111	IV	Cited
Dermal Sensitization	46435112	Nonsensitizer	Cited

LABELING

1. No labeling is required for this product, but the precautionary statements and the the first aid statements are **acceptable**.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 6, 2015

MEMORANDUM

Subject: Human Health and Ecological Risk Assessment of the Proposed Registration of a New End-Use-Product as *BUSAN® 1474 EUP* Containing Ammonia Active Ingredient to Produce Monochloroamine for Oil and Gas Production System

PC Code(s): 005601	DP Barcode(s)/No(s): 425553
Decision No.: 958589	Registration Number (s): 1448-UUE
Petition No(s).: NA	Regulatory Action: PRIA3
Risk Assess Type: Single Chemical	Case No(s): NA
TXR No.: NA	CAS No(s): 7783-20-2
MRID No(s).: NA	40 CFR: NA

From: Jenny J Tao, Toxicologist
Nathan Mottl, Biologist
James Breithaupt, Agronomist
William Erickson, Biologist
Risk Assessment Science Support Branch (RASSB)
Antimicrobials Division (AD) (7510P)

Thru: Timothy Leighton, Senior Scientist, Team Leader
Laura Parsons, Associate Branch Chief
Steven Weiss, Branch Chief
Risk Assessment Science Support Branch (RASSB)
Antimicrobials Division (AD) (7510P)

To: Drusilla Copeland, Product Reviewer
Velma Noble, Product Manager, Team 31
John Hebert, Branch Chief
Regulatory Management Branch 1
Antimicrobials Division (7510P)

The Agency has conducted a human health and ecological risk assessment for the proposed registration of ammonia as an active ingredient to produce monochloramine to be used in the oil and gas production system. As discussed on the following pages, there are no risks of concern for either ammonia or monochloroamine.

BACKGROUND

The registrant, Buckman Laboratories, Inc., submitted an application for a new end-use product (EUP), *BUSAN® 1474 EUP*, containing 7.59% of the ammonia active ingredient (a.i.). According to the submitted proposed label, *BUSAN® 1474 EUP* is applied in conjunction with sodium hypochlorite to form monochloramine, an oxidizing microbiocide, to help control algae, bacteria, fungi, archaea, and other microorganisms in waters used in oil and gas production, such as drilling, stimulation, hydraulic fracturing, production, and disposal operations. The new product is added, by the Buckman-trained system operator, to dilution water to achieve a minimum molar ratio of 1 part *BUSAN® 1474 EUP* to 1 part sodium hypochlorite, using a closed metered chemical feed system, to achieve a residual concentration of at least 1 part per million (ppm) in excess of the system oxidant demand. Treatment rates may be reduced 50-80% of system oxidant demand, using either continuous or intermittent application to achieve uniform mixing, once the minimum 1 ppm residual concentration is achieved.

HUMAN HEALTH HAZARD CHARACTERIZATION

Ammonia

Acute Toxicity

The registrant's "cited-all" acute toxicity studies indicated that ammonia is of low acute toxicity for all routes (i.e. Toxicity Category IV) based on LD_{50} of > 5000 mg/kg in rats for oral and dermal toxicity and LC_{50} of ≥ 2.08 mg/L (4-hour) in rats for inhalation toxicity. It is minimally irritating to the eyes and slightly irritating to the skin (Toxicity Category IV for both) based on the primary eye and dermal irritation studies; both were conducted in rabbits. Ammonia is not a dermal sensitizer based on the dermal sensitization study in guinea pigs.

Subchronic and Chronic Toxicity, Carcinogenicity, and Mutagenicity

Ammonia poses low oral toxicity at dose level of up to 2000 mg/kg/day in rats. There were no changes observed in the body weights, organ weights, hematological, serum biochemical, or histopathological examinations that contributed to ammonia toxicity. There were no effects on arterial blood gases and no observation of histopathological changes in the lower respiratory tract in a 14-day inhalation study in rats. Body weights of the test animals were unaffected as well. There are no dermal studies available for ammonia.

There were no maternal mortality or no treatment-related signs of clinical toxicity observed; developmental parameters were not affected in rats nor in mice, via oral exposure route (gavage or in drinking water).

Significant increases in absolute and relative kidney weights and relative liver weight were noted in males (all $p<0.05$) and females (absolute kidney weight only; $p<0.01$) in rats at the high dose in a dietary chronic study, but no effects were found on survival rate, body weights, food consumptions, hematological, serum biochemistry or histological parameters at any dose levels tested. Ammonia was found to be nonmutagenic and was not carcinogenic in a dietary study in rats.

There are no metabolism studies for ammonia. Absorbed ammonia is transported to the liver and then metabolized to urea and excreted via the kidneys. Ammonia is also an endogenous substance that serves a major role in the maintenance of the acid-base balance.

Monochloramine

The developmental and reproductive toxicity of monochloramine has been examined in rats, but with suboptimal studies. However, due to the chemical relationship between monochloramine and chlorine, the Agency believes that the reproductive and developmental studies for chlorine may also be used to character the hazard of monochloramine.

There were no statistical differences in fertility, viability, litter size, day of eye opening or average day of vaginal patency between control and test animals in a reproductive study (by gavage) of chloramines in rats (MRID 48865602). There were also no alterations in sperm count, direct progressive sperm movement, percent mobility or sperm morphology in adult males. Weights of male and female reproductive organs were not significantly different among control and test groups, and there were no significant morbid anatomic changes evident on tissue examination. No signs of toxicity, changes in blood counts, or effects on body weight were observed in adult rats or either sex at any dose level. The mean weight of the pups was not affected by chloramines treatment. Additionally, no maternal of developmental effects were observed in a drinking water study of monochloramine in rats (MRID 48865601).

The long-term effects of chloraminated water were examined in both rats and mice in a National Toxicology Program study (NTP, 1992). In both species, there were no statistically significant findings attributable to chemical exposure at the highest dose tested. The no-observed-adverse-effect-level (NOAEL) in rats was chosen as the basis for the chronic oral reference dose (RfD) by U.S. EPA (US EPA 2005).

Monochloramine is not mutagenic. Although a marginal increase in mononuclear cell leukemia was observed in female F344/N rats in a two-year bioassay, monochloramine is not classifiable as to human carcinogenicity (Group D) based on inadequate human data and equivocal evidence of carcinogenicity from animal bioassays.

HUMAN EXPOSURE AND RISK ASSESSMENT

Occupational Exposures

BUSAN® 1474 EUP which contains ammonium is intended to be used in conjunction with sodium hypochlorite in makeup, recycled, flowback, injection, and produced fluid waters associated for oil and gas production (i.e., drilling, stimulation, hydraulic fracturing, production, and disposal operations). The proposed label restricts application to automated closed metered delivery systems. Automated closed mixing and loading systems protect occupational workers from dermal and inhalation exposures. As a result, occupational handler exposures are expected to be minimal and a quantitative occupational handler risk assessment is not necessary.

BUSAN® 1474 EUP when combined with sodium hypochlorite and introduced into the oil/gas well waters creates diluted aqueous monochloramine (MCA). The reaction could potentially

produce trichloramine, which is more volatile. However, the label specifies that the breakdown products should be monitored and controlled. Based on the specific label directions that monitor and control breakdown products, dilute applications, and the limited worker contact to the treated water used for oil and gas operations (immediate injection of the treated water into pipes that go down into the borehole of the well), post-application exposures for oil/gas uses are expected to be minimal and a quantitative occupational post-application risk assessment was not necessary.

Residential Exposure

No residential exposure scenarios are associated with the proposed uses of ammonium.

Dietary and Drinking Water Exposures

No drinking water risks are expected from the proposed uses of ammonia. EPA has established a maximum residual disinfectant level (MRDL) of 4.0 ppm for chlorine (which includes chlorine from monochloramine) and water utilities are required to maintain chlorine at or below this MRDL. The registrant also indicated (Barbee, 2015) that there were control points to ensure a "precise manufacturing of 100% Monochloramine (MCA)" and that there would be no formation and distribution of dichloramine and trichloramine during the treatment and in the discharge water after treatment by maintaining a pH values at ~11. Consequently, most, if not all, of the *monochloroamine will be consumed during the treatment process and minimum to no* dichloramine and trichloramine would exist in the discharge water after treatment. The Agency does not anticipate any drinking water risks of concern.

Aggregate Exposures

As there are no dietary (food or drinking water) or residential exposures associated with the proposed uses of ammonium, there is no need to estimate aggregate exposures based on the proposed uses.

CUMULATIVE RISK

EPA does not have, at this time, available data to determine whether ammonia has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. This chemical is of low systemic toxicity and no adverse effects on human health are expected, other than eye irritation from acute exposure. For the purposes of this Section 3 *registration action; therefore, EPA has assumed that ammonium does not have a common* mechanism of toxicity with other substances largely because it elicits no adverse effects in mammals.

ENVIRONMENTAL FATE AND EXPOSURE

Ammonia

Routine ammonia releases or discharges to the environment are not anticipated for the proposed use because the product is mixed with sodium hypochlorite in a closed system to produce

monochloramine. Releases or discharges would only occur as a result of a system failure or spill and such situations are covered by the precautionary statements on the product label.

Monochloroamine

Monochloramine exposures to the environment are not of concern for the proposed oil and gas use because of high reactivity of monochloroamine and the fact that the maximum treatment rate of 4 ppm monochloramine (as Cl_2) does not exceed the EPA maximum residual disinfectant level (MRDL) of 4.0 ppm. Monochloramines undergo autodecomposition to form N_2 gas and also react with natural organic matter (NOM), bromide, and nitrite (Duirk et al., 2005). In addition, the proposed Busan® 1474 label requires re-treatment for 5-60 minutes every hours, which indicates that high reactivity is occurring with the proposed use. As a result, the Agency does not anticipate significant environmental exposure from the proposed use in oil and gas.

ECOLOGICAL EFFECTS AND RISK ASSESSMENT

Ammonia

For the reasons discussed above, ammonia is not expected to be released into the environment. Therefore, risks to nontarget organisms are not anticipated.

Monochloroamine

The Agency does not anticipate significant environmental exposure of nontarget organisms to monochloramine from the proposed use in oil and gas. However, monochloramines are highly toxic to aquatic organisms (EPA 1985), and any release into the aquatic environment has a potential to adversely affect fish, aquatic invertebrates, and aquatic plants. The proposed product label does not specifically preclude release of chlorine residues in discharge water. If the statement below is added for oil and gas production, than the Agency would presume minimal exposure and a risk assessment is not needed.

> "Chloramine levels must be monitored. If chloramine is detected, it must be neutralized to levels below 2 ppb for freshwater and 3 ppb for saltwater by the addition of sodium metabisulfite."

ENDOCRINE DISRUPTION

As required under FFDCA section 408(p), EPA has developed the Endocrine Disrupter Screening Program (EDSP) to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA

will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. This list of chemicals was selected based on the potential for human exposure through pathways such as food and water, residential activity, and certain post-application agricultural scenarios. This list should not be construed as a list of known or likely endocrine disrupters.

Ammonia is not among the group of 58 pesticide active ingredients on the initial list to be screened under the EDSP. Under FFDCA sec. 408(p) the Agency must screen all pesticide chemicals. Accordingly, EPA anticipates issuing future EDSP test orders/data call-ins for all pesticide active ingredients. For further information on the status of the EDSP, the policies and procedures, the list of 67 chemicals, the test guidelines and the Tier 1 screening battery, please visit our website: http://www.epa.gov/endo/.

REFERENCES

MRID 48865601 Abdel-Rahman, M.S., Berardi, M.R., and Bull, R.J. (1982). Effect of chlorine and monochloramine in drinking water on the developing rat fetus. J. Appl. Toxicol. 2:156-9.

MRID 48865602 Carlton, B.D., Barlett, P., and Basaran, A., et al. (1986). Reproductive Effects of Alternate disinfectants. Environ. Health Perspect. 69:237-41.

Barbee, D (2015). Email communication with an attachment in response to the Agency's inquiries. Dated Wednesday, March 04, 2015 @ 10:52 AM.

Duirk, S.E., B. Gomert, and J.P. Croue, et al. (2005). Modeling monochloramine loss in the presence of natural organic matter. Water Research 39:3418-3431.

National Toxicology Program (NTP). (1992). Toxicology and Carcinogenesis Studies of Chlorinated and Chloraminated Water (CAS Nos. 7782-50-5, 7681-52-9, and 10599-90-3) in F344/N Rats and B6C3F1 Mice (drinking water studies). NTP TR 392, National Institutes of Health.

U. S. EPA (2005). Integrated Risk Information System (IRIS): Monochloramine (CASRN 10599-90-3). http://www.epa.gov/iris/subst/0644.htm accessed on March 25, 2015.

U. S. EPA (2002). Integrated Risk Information System (IRIS): Chlorine (CASRN 7782-50-5). http://www.epa.gov/iris/subst/0405.htm accessed on March 25, 2015.

U. S. EPA (1985). Ambient Water Quality Criteria for Chlorine – 1984. U.S. EPA Office of Water, EPA 440/5-84-030, January, 1985.

3/4/15 Jenny also

Copeland, Drusilla

From: Dennis Barbee <dlbarbee@buckman.com>
Sent: Wednesday, March 04, 2015 10:52 AM
To: Copeland, Drusilla
Cc: Carl Watson; Jeff Thorne; Ted Sumrall; Rob Quarles, III; Dennis Barbee
Subject: RE: 1448-UUE
Attachments: Busan 1474 EPA Response 030415.docx

Hi Drusilla, As requested in the e-mail below, please find attached the Buckman response to the Science Branch request. Please do not hesitate to contact me if you have any additional questions. Dennis

Dennis L. Barbee, Ph.D.
Associate Director, Regulatory Affairs
Buckman North America
901.272.8248 Office
901.272.6256 Fax

email: dlbarbee@buckman.com

buckman.com

Commitment makes the best chemistry

From: Copeland, Drusilla [mailto:Copeland.Drusilla@epa.gov]
Sent: Tuesday, February 24, 2015 1:50 PM
To: Dennis Barbee
Subject: FW: 1448-UUE

Hi Dennis this the email below that I emailed to Carl Watson. If you can response that would help our science people.

Drusilla Copeland
Environmental Protection Specialist
Voice: 703 308-6224
Fax: 703 308-8481
copeland.drusilla@epa.gov

From: Copeland, Drusilla
Sent: Tuesday, February 24, 2015 10:09 AM
To: Carl Watson
Cc: Mottl, Nathan; Erickson, William; Breithaupt, James; Tao, Jenny; Noble, Velma; Copeland, Drusilla
Subject: 1448-UUE

Good morning, this is in reference to the information in which you submitted back to the Agency regarding your 10 day deficiency letter. The information in which you provided was sent to the science branch and they have a question that needs to be addressed.

1. Based on the revised label, the agency is still not clear about how the system pH would be controlled to prevent the formation of the byproducts of dichloramine and trichloramine, which bear risk concerns.

Buckman
NORTH AMERICA

Buckman Laboratories, Inc.
1256 North McLean Blvd.
Memphis, TN 38108-1241 USA

(901) 278-0330 Tel
(901) 276-5343 Fax
buckman.com

Via Email

February 6, 2015

Drusilla Copeland, Product Reviewer
USEPA, OPP, AD, RMB I (PM 31)
Room S4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202

Re: Response to Technical Screen Comments
EPA Registration No: 1448-UUE, BUSAN 1474
Barcode No: 423827

Please find attached a copy of the draft label which contains revised use direction language intended to address Agency comments/concerns contained in the Technical Screen document of the label for the proposed registration of a new end-use product, BUSAN 1474, dated 01/28/15. Buckman hopes that these changes will allow the application to pass the screen and review process.

This application for monochloramine (MCA) is for use in drilling, stimulation, hydraulic fracturing, production, and disposal operations. These environments have a very high brine concentration and a high concentration of reducing agents (such as Iron (II) Sulfate), which will react with any residual MCA. Therefore, no residual MCA is anticipated after exposure to downhole conditions. Because of MCA's long history of use in the treatment of drinking water, Buckman believes that the use has a more favorable environmental profile from the context that: no bioaccumulation or long term effects are expected to occur (MCA is not persistent in the environment); the decomposition by-products are much less than chlorination and AOX formation is significantly reduced, unlike chlorine and other halogen containing biocides.

Currently, for downhole and pipeline oil and gas operations, less environmentally friendly biocides are being used. MCA may be considered a "safer" alternative for hydraulic fracturing and for pipeline applications as residual MCA is not expected to exceed the MRDL which has been assessed for environmental and human health safety. However, if they do, a neutralization process is available.

If you have any questions or require any additional information regarding this application, please feel free to contact me.

Sincerely,
BUCKMAN LABORATORIES, INC.

Carl F. Watson, Ph.D.
Sr. Regulatory Toxicologist

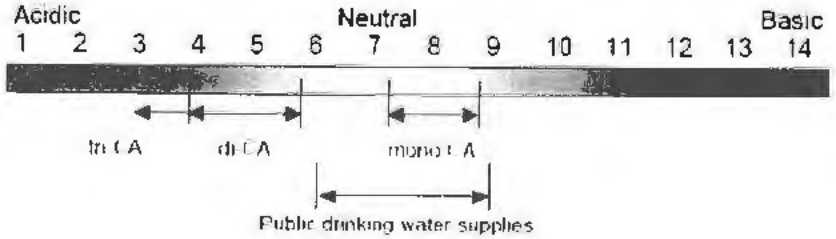
The precise manufacturing of 100% Monochloramine (MCA) will be assured via an MCA generator unit which has multiple control points.

Control Point 1: Initially, manufacturing specifications of the raw ingredients will ensure that the two primary constituents (Busan 1474 and Bulab 6004 (Sodium Hypochlorite or "Bleach")) will have pH values of ≥ 9 and ≥ 12 respectfully, prior to release from manufacturing. As shown in Figure-1, Dichloramine and Trichloramine will not form at pH values above 6 and public drinking water supplies are therefore kept above this pH.

Figure - 1: Relationship between pH and Mono, Di and Trichloramine Formation **Buckman**

pH ranges

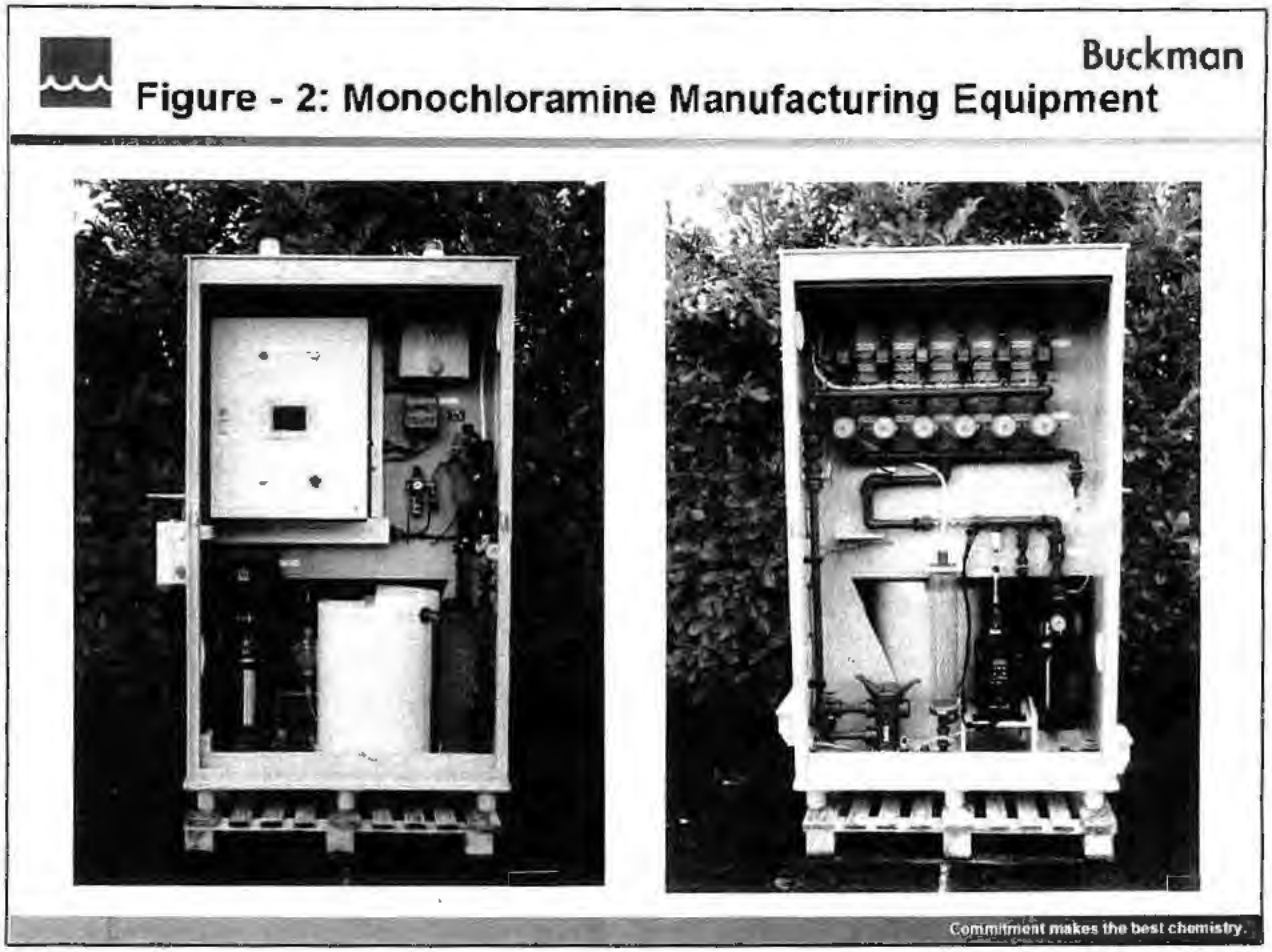
Monochloramine is the first member of the homologous series and is the principal product formed at pH 7.5-9. However, higher chlorine concentrations in the water and lower pH results in the formation of di- and tri-chloramine.



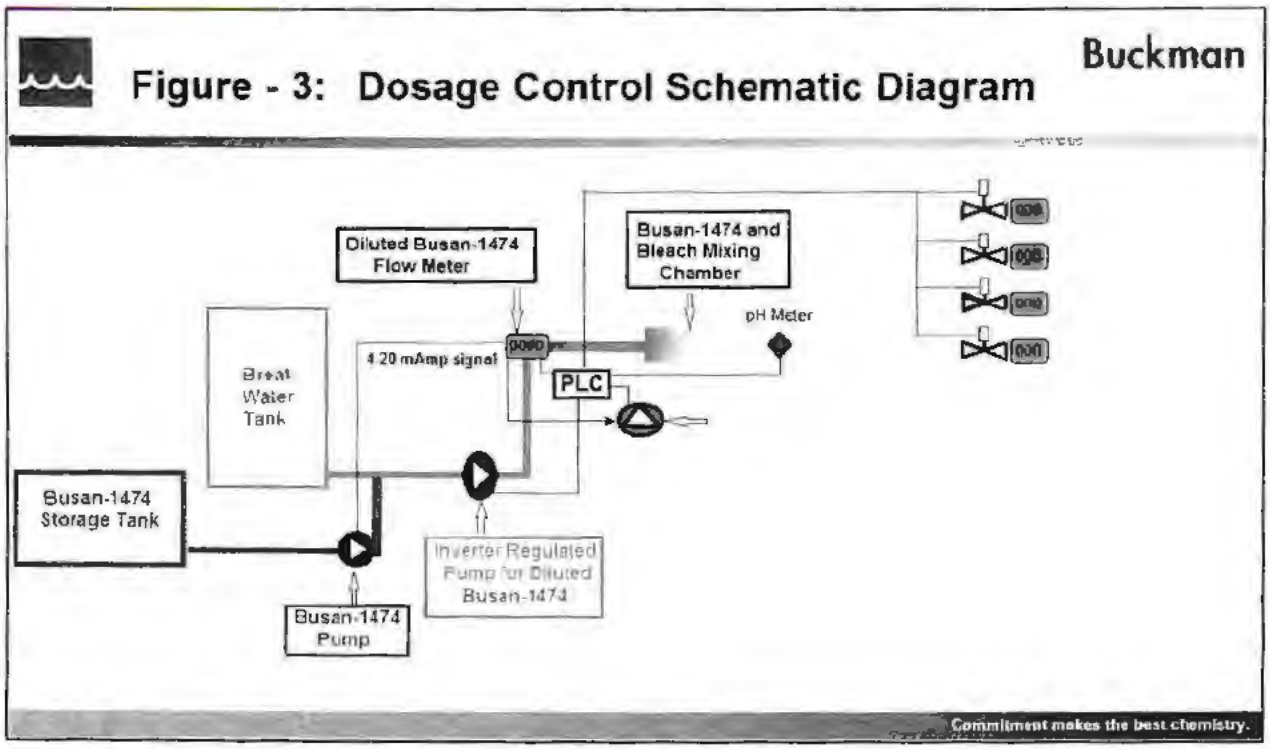
From: ***Chemicals in Drinking Water: Chloramines.*** **Scottish Centre for Infection and Environmental Health website at:** www.show.scot.nhs.uk/scieh/environmental/enviropdf/Chloramines.pdf

Commitment makes the best chemistry.

Control Point 2: The mixing equipment (Figure-2) will always ensure that The Cl:N ratio is 1:1 or less. In other words, there is never an excess of chlorine present which could lead to the formation of Dichloramine and Trichloramine. The MCA mixing equipment will ensure 100% MCA preparation via Programmable Logic Control (PLC) inputs and will control the exact addition rates to ensure precise equimolar mixing ratios. The pH of the reaction mixture is always alkaline. At no time does the pH drop below ~11.



Control Point 3: As shown in Figure-3, the Programmable Logic Controller (PLC) will have input from a strategically placed pH meter which will measure the pH of the MCA prior to pumping to the applications. This data will feed into the PLC such that the PLC will order system shut down and prevent additional mixing of the Bulab 1474 and Sodium Hypochlorite as well as prevent pumping into the application if not within the required pH ranges, thus preventing the formation and distribution of Dichloramine or Trichloramine.


Buckman
Figure - 3: Dosage Control Schematic Diagram
Diluted Busan-1474 Flow Meter
Busan-1474 and Bleach Mixing Chamber
pH Meter
4-20 mAmp signal
PLC
Busan-1474 Storage Tank
Busan-1474 Pump
Inverter Regulated Pump for Diluted Busan-1474
Commitment makes the best chemistry.

(a) *Sale by registrant or producer.* (1) No product with a use classified for restricted use may be distributed or sold by the registrant or producer after the 120th day after the effective date of such classification unless the product:

(i) Bears an approved amended label which contains the terms of restricted use imposed by the Agency and otherwise complies with part 156 of this chapter;

(ii) Bears a sticker containing the product name, EPA registration number, and any terms of restricted use imposed by the Agency; or

(iii) Is accompanied by supplemental labeling bearing the information listed in paragraph (a)(1)(ii) of this section.

(2) If the registrant chooses to delete the restricted uses from his product label, that product may not be distributed or sold after the 180th day after the effective date of classification unless the product bears amended labeling with the restricted uses deleted.

(3) Notwithstanding paragraphs (a)(1) and (2) of this section, after the 270th day after the effective date of classification, no registrant or producer may distribute or sell a product that does not bear the approved amended label. After that date, stickers and supplemental labeling described in paragraph (a)(1) (ii) and (iii) are no longer acceptable.

(b) *Sale by retailer.* No product with a use classified for restricted use by a regulation may be distributed or sold by a retailer or other person after the 270th day after the effective date of the final rule unless the product bears a label or labeling which complies with paragraph (a)(1) of this section.

§ 152.168 Advertising of restricted use products.

(a) Any product classified for restricted use shall not be advertised unless the advertisement contains a statement of its restricted use classification.

(b) The requirement in paragraph (a) of this section applies to all advertisements of the product, including, but not limited, to:

(1) Brochures, pamphlets, circulars and similar material offered to purchasers at the point of sale or by direct mail.

(2) Newspapers, magazines, newsletters and other material in circulation or available to the public.

(3) Broadcast media such as radio and television.

(4) Telephone advertising.

(5) Billboards and posters.

(c) The requirement may be satisfied for printed material by inclusion of the statement "Restricted Use Pesticide," or the terms of restriction, prominently in the advertisement. The requirement may be satisfied with respect to broadcast or telephone advertising by inclusion in the broadcast of the spoken words "Restricted use pesticide," or a statement of the terms of restriction.

(d) The requirements of this section shall be effective:

(1) After 270 days after the effective date of restriction of a product that is currently registered, unless the Agency specifies a shorter time period;

(2) Upon the effective date of registration of a product not currently registered.

§ 152.170 Criteria for restriction to use by certified applicators.

(a) *General criteria.* An end-use product will be restricted to use by certified applicators (or persons under their direct supervision) if the Agency determines that:

(1) Its toxicity exceeds one or more of the specific hazard criteria in paragraph (b) or (c) of this section, or evidence described in paragraph (d) of this section substantiates that the product or use poses a serious hazard that may be mitigated by restricting its use;

(2) Its labeling, when considered according to the factors in paragraph (e)(2) of this section, is not adequate to mitigate these hazard(s);

(3) Restriction of the product would decrease the risk of adverse effects; and

(4) The decrease in risks of the pesticide as a result of restriction would exceed the decrease in benefits.

(b) *Criteria for human hazard*—(1) *Residential and institutional uses.* A pesticide product intended for residential or institutional use will be considered for restricted use classification if:

(i) The pesticide, as diluted for use, has an acute oral LD_{50} of 1.5 g/kg or less;

(ii) The pesticide, as formulated, has an acute dermal LD_{50} of 2000 mg/kg or less;

(iii) The pesticide, as formulated, has an acute inhalation LC_{50} of 0.5 mg/liter or less, based upon a 4-hour exposure period;

(iv) The pesticide, as formulated, is corrosive to the eye (causes irreversible destruction of ocular tissue) or results in corneal involvement or irritation persisting for more than 7 days;

(v) The pesticide, as formulated, is corrosive to the skin (causes tissue destruction into the dermis and/or scarring) or causes severe irritation (severe erythema or edema) at 72 hours; or

(vi) When used in accordance with label directions, or widespread and commonly recognized practice, the pesticide may cause significant subchronic, chronic or delayed toxic effects on man as a result of single or multiple exposures to the product ingredients or residues.

(2) *All other uses.* A pesticide product intended for uses other than residential or institutional use will be considered for restricted use classification if:

(i) The pesticide, as formulated, has an acute oral LD_{50} of 50 mg/kg or less;

(ii) The pesticide, as formulated, has an acute dermal LD_{50} of 200 mg/kg or less;

(iii) The pesticide, as diluted for use, has an acute dermal LD_{50} of 16 g/kg or less;

(iv) The pesticide, as formulated, has an acute inhalation LC_{50} of 0.05 mg/liter or less, based upon a 4-hour exposure period;

(v) The pesticide, as formulated, is corrosive to the eye or causes corneal involvement or irritation persisting for more than 21 days;

(vi) The pesticide, as formulated, is corrosive to the skin (causes tissue destruction into the dermis and/or scarring); or

(vii) When used in accordance with label directions, or widespread and commonly recognized practice, the pesticide may cause significant subchronic toxicity, chronic toxicity, or delayed toxic effects on man, as a result of single or multiple exposures to the product ingredients or residues.

(c) *Criteria for hazard to non-target species*—(1) *All products.* A pesticide product intended for outdoor use will be considered for restricted use classification if:

(i) When used according to label directions, application results in residues of the pesticide, its metabolites, or its degradation products, in the diet of exposed mammalian wildlife, immediately after application, such that:

(A) The level of such residues equals or exceeds one-fifth of the acute dietary LC_{50}; or

(B) The amount of pesticide consumed in one feeding day (mg/kg/day) equals or exceeds one-fifth of the mammalian acute oral LD_{50};

(ii) When used according to label directions, application results, immediately after application, in residues of the pesticide, its metabolites or its degradation products, in the diet of exposed birds at levels that equal or exceed one-fifth of the avian subacute dietary LC_{50};

(iii) When used according to label directions, application results in residues of the pesticide, its metabolites or its degradation products, in water that equal or exceed one-tenth of the acute LC_{50} for non-target aquatic organisms likely to be exposed; or

(iv) Under conditions of label use or widespread and commonly recognized practice, the pesticide may cause discernible adverse effects on non-target organisms, such as significant mortality or effects on the physiology, growth, population levels or reproduction rates of such organisms, resulting from direct or indirect exposure to the pesticide, its metabolites or its degradation products.

(2) *Granular products.* In addition to the criteria of paragraph (c)(1) of this section, a pesticide intended for outdoor use and formulated as a granular product will be considered for restricted use classification if:

(i) The formulated product has an acute avian or mammalian oral LD_{50} of 50 mg/kg or less as determined by extrapolation from tests conducted with technical material or directly with the formulated product; and

(ii) It is intended to be applied in such a manner that significant exposure to birds or mammals may occur.

(d) *Other evidence.* The Agency may also consider evidence such as field studies, use history, accident data, monitoring data, or other pertinent evidence in deciding whether the product or use may pose a serious hazard to man or the environment that can reasonably be mitigated by restricted use classification.

(e) *Alternative labeling language.* (1) If the Agency determines that a product meets one or more of the criteria of paragraphs (b) or (c) of this section, or if other evidence identified in paragraph (d) of this section leads the Agency to conclude that the product should be considered for restricted use classification, the Agency will then determine if additional labeling language would be adequate to mitigate the identified hazard(s) without restricted use classification. If the labeling language meets all the criteria specified in paragraph (e)(2) of this section, the product will not be classified for restricted use.

(2) The labeling will be judged adequate if it meets all the following criteria:

(i) The user, in order to follow label directions, would not be required to perform complex operations or procedures requiring specialized training and/or experience.

(ii) The label directions do not call for specialized apparatus, protective equipment, or materials that reasonably would not be available to the general public.

(iii) Failure to follow label directions in a minor way would result in few or no significant adverse effects.

(iv) Following directions for use would result in few or no significant adverse effects of a delayed or indirect nature through bioaccumulation, persistence, or pesticide movement from the original application site.

(v) Widespread and commonly recognized practices of use would not nullify or detract from label directions such that unreasonable adverse effects on the environment might occur.

§ 152.171 Restrictions other than those relating to use by certified applicators.

The Agency may by regulation impose restrictions on a product or class of products if it determines that:

(a) Without such restrictions, the product when used in accordance with warnings, cautions and directions for use or in accordance with widespread and commonly recognized practices of use may cause unreasonable adverse effects on the environment; and

(b) The decrease in risks as a result of restricted use would exceed the decrease in benefits as a result of restricted use.

§ 152.175 Pesticides classified for restricted use.

The following uses of pesticide products containing the active ingredients specified below have been classified for restricted use and are limited to use by or under the direct supervision of a certified applicator.

Active ingredient	Formulation	Use pattern	Classification[1]	Criteria influencing restriction
Acrolein	As sole active ingredient. No mixtures registered	All uses	Restricted	Inhalation hazard to humans. Residue effects on avian species and aquatic organisms.
Aldicarb	As sole active ingredient	Ornamental uses (indoor and outdoor)	do	Other hazards—accident history.
	No mixtures registered	Agricultural crop uses	Under further evaluation	
Aluminum phosphide	As sole active ingredient. No mixtures registered	do	do	Inhalation hazard to humans.
Azinphos methyl	All liquids with a concentration greater than 13.5 pct	do	do	Do
	All other formulations	do	Under further evaluation	

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. Carl Watson, Ph.D.
Buckman Laboratories, Inc
1256 N. McLean Blvd
Memphis, TN 38108

JAN 28 2015

Subject: **BUSAN 1474**
EPA Registration Symbol: 1448-UUE
Application Dated September 30, 2014
EPA Received October 1, 2014

Dear Mr. Watson:

The Agency has completed its preliminary technical screening of your application pursuant to Section 33(f)(4)(B)(i)(II) of the Federal Insecticide, Fungicide, and Rodenticide (FIFRA) Act, as amended by the Pesticide Registration Improvement Extension Act. The Agency has determined that your application has not passed the preliminary technical screen and therefore is subject to rejection if the application is not corrected.

The submission has failed the 45 day Technical Screen (See attachment dated 1/28/2015)

In order for the review of your product to continue, you will need to correct your application to address the item(s) listed above within 10 business days of the date you received this letter. Corrections must be received by EPA by the 10th business day. EPA recommends sending your complete set of corrections by email to the contact listed below to ensure they are timely received. If studies or confidential information are being submitted by mail, a complete courtesy copy received by email by the deadline will be considered timely. If you cannot correct the application [or do not respond] within 10 business days, your application will be rejected.

At this time you could also choose to withdraw your application. If you have questions, please contact Velma Noble at Noble.Velma@epa.gov or 703 308 6233 or at Copeland.Drusilla@epa.gov or 703-308-6224.

Sincerely,

Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

Attachment: Toxicologist review dated 1/28/15

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 28, 2015

MEMORANDUM

Subject: Technical Screen for Treatment of Water Systems Used in Oil and Gas Production with Ammonia

PC Code(s): 005601	DP Barcode(s)/No(s): 423827
Decision No.: 495990	Registration Number (s): 1448-UUE
Petition No(s).: NA	Regulatory Action: PRIA3 Technical Screen
Risk Assess Type: Single Chemical	Case No(s): NA
TXR No.: NA	CAS No(s): 7783-20-2
MRID No(s).: NA	40 CFR: NA

From: Jenny J. Tao, Toxicologist
James Breithaupt, Agronomist
William Erickson, Biologist
Nathan Mottl, Biologist
Risk Assessment Science Support Branch (RASSB)
Antimicrobials Division (AD) (7510P)

Thru: Timothy Leighton, Senior Scientist
Laura Parsons, Associate Branch Chief
Steven Weiss, Branch Chief
Risk Assessment Science Support Branch (RASSB)
Antimicrobials Division (AD) (7510P)

To: Drusilla Copeland, Product Reviewer
Velma Noble, Product Manager, Team 31
John Hebert, Branch Chief
Regulatory Management Branch I
Antimicrobials Division (7510P)

The Agency has conducted a technical screen for the proposed registration of a new end-use product, *BUSAN® 1474 EUP*, containing ammonia as the active ingredient (a.i.). *BUSAN® 1474 EUP* is designed to produce monochloramine (when combined with an oxidant, such as sodium hypochlorite), to treat water systems used in oil and gas production. The purpose of the technical screen is to determine whether the data and information submitted with the application and label are sufficient to allow the assessment of human exposure, human toxicology, environmental fate, and ecological toxicology. The application as submitted fails the technical screen based on the proposed labeling submitted. If the label changes described below are made, the application will pass the screen.

Proposed Label (fails the screen)

The registrant, Buckman Laboratories, Inc., submitted an application for a new end-use product (EUP), *BUSAN® 1474 EUP*, containing 7.59% of the ammonia active ingredient (a.i.). According to the proposed label submitted, *BUSAN® 1474 EUP* is applied in conjunction with sodium hypochlorite to form monochloramine, an oxidizing microbiocide, to help control algae, bacteria, fungi, archaea and other microorganisms in waters used in oil and gas production, such as drilling, stimulation, hydraulic fracturing, production, and disposal operations. The new product is added, by the Buckman-trained system operator, to dilution water to achieve a minimum molar ratio of 1 part *BUSAN® 1474 EUP* to 1 part sodium hypochlorite, using a closed metered chemical feed system, to achieve a residual concentration of at least 1 ppm in excess of the system oxidant demand. Treatment rates may be reduced 50-80% of system oxidant demand, using either continuous or intermittent application to achieve uniform mixing, once the minimum 1 ppm residual concentration is achieved.

However, the proposed label does not specify an absolute maximum application rate, a maximum rate above the biological oxidant demand, or additional details on application. In contrast, the label for a currently registered product, *Busan® 1215*, which also contains 7.59% of ammonia as the a.i. for uses in pulp and paper mills and industrial water systems, provides additional details, including the duration, timing, and concentration of intermittent applications.

Additionally, the proposed label does not address the disposal of the oilfield water. Oilfield water is eventually placed into holding ponds for evaporation, injected into deep wells, or treated in a wastewater treatment plant (WWTP). The registrant needs to address the potential need for neutralization in these disposal situations to ensure that no chloramine-posed risks exist in the discharges. For example, the *Busan® 1215* label requires neutralization of chloramines using sodium metabisulfite until chloramine is not detected, regardless of whether the effluent does or does not pass through a waste water treatment plant.

Human Exposure (passes the screen)

BUSAN® 1474 EUP contains 7.59% of the ammonia active ingredient (a.i.), which is the equivalent concentration in aqueous household ammonia, which typically contains concentrations of 5 to 10% ammonia in water (OSHA, 2014). The proposed labeling statement requires baseline personal protection (e.g. long pants and long sleeved shirt) and restricts application to closed metered delivery systems and Buckman-trained system operators. As a result of the label precautions, such as the closed mixing/loading statement and operator training, occupational handler exposures are expected to be minimal.

Although concentrations are expected to be diluted, the proposed label does not specify a maximum application rate. Potential bystander inhalation effects would occur if workers were exposed to high concentrations of diluted ammonia or monochloramine. OSHA currently regulates inhalation exposure to ammonia concentrations as low as 50 ppm based on respiratory tract irritation effects (OSHA, 2012; NIOSH, 2011). In addition, mixing solutions of ammonia and sodium hypochlorite also results in acrid monochloramine and dichloramine fumes. Inhalation of chloramine fumes from mixing household cleaning agents (ammonia and sodium hypochlorite bleach) at high concentrations results in burning in eyes and throat, transient cough,

dyspnea, nausea and vomiting (Health Canada, 2014). Since, no maximum concentration limits are imposed on the proposed label, the Agency has concerns for potential bystander inhalation exposures. No additional occupational exposure data are required, however. The post-application inhalation concern would be mitigated with imposing an application rate limit.

No dietary (food) risks are expected to be associated with the proposed new uses of *BUSAN® 1474 EUP*, since it is only used in the non-food related settings.

The Agency has established a maximum residual disinfectant level (MRDL) of 4.0 ppm for chlorine (which includes chlorine from monochloramine) and water utilities are required to maintain chlorine at or below this MRDL. If the proposed label is revised to demonstrate that negligible level of monochloramine exists at the point of discharge and most of the monochloroamine is consumed during the treatment process, then it is highly unlikely that drinking water exposures to monochloramine from the proposed new uses will result in risks of concern.

Toxicology (passes the screen)

As indicated in the Ammonia and Ammonium Sulfate Registration Review Final Work Plan (EPA, 2013), the Agency does not anticipate requiring additional toxicology studies to support the currently registered pesticide uses. Additionally, repeated-dose toxicology studies and endpoints for risk assessment are available in the Agency's database for monochloramine. For the proposed new uses, if the registrant submits a revised label that demonstrates a low potential for human exposure to ammonia and/or monochloramine, no additional toxicity studies are anticipated to be required to assess human hazards to either chemical.

Environmental Fate (passes the screen)

Guideline environmental fate data for monochloramines are not required because this is an inorganic substance and the test guidelines are not relevant. Adequate environmental fate data are available in the D342580 review (Gowda, 2008; D342580), which was based on the EPI-Suite model and numerous literature sources cited in the review document.

Ecological Effects (passes the screen)

The Agency has sufficient monochloromine ecotoxicity data for freshwater and estuarine/marine fish, invertebrates, and plants to support this oil and gas production water systems use. Chronic ecotoxicity data are not available; however, because monochloromine rapidly biodegrades, chronic exposure is not anticipated and chronic data are not anticipated to be needed.

Four acute ecotoxicology studies (avian, freshwater fish, invertebrate and green algae) are required for any product to determine if precautionary statements are needed on the product label and to provide a basic data set in case of a spill or product misuse. The agency has adequate data for product labeling. The registrant may need to provide compensation for these data as appropriate.

No additional ecotoxicity data are needed for either ammonia or monochloramine to support the proposed new use.

References

1. Gowda, Srinivas. 2008. Environmental Fate Assessment of Aqueous Ammonia (7.59% Total) for the Proposed Use in Industrial Water Systems. March 10, 2008. DP Barcode D342580.

2. Health Canada. 2014. Guidelines for Canadian Drinking Water Quality – Technical Documents: Chemical/Physical Parameters – Chloramines. Health Canada Reports and Publications on Water Quality, October 31, 2014. http://www.hc-sc.gc.ca/ewh-semt/pubs/water-eau/chloramines/index-eng.php Accessed on December 16, 2014.

3. National Institute for Occupational Safety and Health (NIOAH). 2011. 1988 OSHA PEL Project Documentation. NIOSH, Education and Information Division, September 28, 2011. http://www.cdc.gov/niosh/pel88/7664-41.html Accessed on December 16, 2014.

4. Occupational Safety and Health Administration (OSHA). 2012. NIOSH Pocket Guide to Chemical Hazards: Chemical Sampling Information. September 6, 2012. https://www.osha.gov/dts/chemicalsampling/data/CH_218300.html Accessed on December 19, 2014.

5. U. S. Environmental Protection Agency (US EPA). 2013. Ammonia and Ammonium Sulfate Registration Review Final Work Plan. Posted on February 20, 2013. www.regulations.gov Document ID EPA-HQ-OPP-2012-0684.

Buckman
NORTH AMERICA

Buck Laboratories, Inc.
1256 North McLean Blvd.
Memphis, TN 38108-1241 USA

(901) 278-0330 Tel
(901) 276-5343 Fax
buckman.com

Via Federal Express

September 30, 2014

US Environmental Protection Agency
Document Processing Desk (REGFEE)
Office of Pesticide Programs, Antimicrobial Division (PM 31)
Room S4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202

Re: BUSAN 1474 - Application for New Pesticide Product

Enclosed please find an application for a new product registration for Buckman Laboratories, Inc. product: BUSAN 1474 - EUP. Enclosed you will find the following information to support this application:

- PRIA Fee Category: EPA No.: ~~A540;~~
  CR No. 476: New use, non-food, outdoor, FIFRA sec. 2(mm) uses
- PRIA Fee Payment: Check - $18,234.00
- Form 8570-1, Application under PRIA
- Form 8570-4, Three (3) copies of Confidential Statement of Formula
- Form 8570-34, Certification with Respect to Citation of Data
- FORM 8570-35, Data Matrix
- Five (5) Copies of the Draft Labeling

If you have any questions or require any additional information regarding this application, please feel free to contact me.

Sincerely,
BUCKMAN LABORATORIES, INC.

Carl F. Watson, Ph.D.
Sr. Regulatory Toxicologist

Please read instructions on reverse before pleting form. Form Ap d. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☑ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number
1448-_____

2. EPA Product Manager
Velma Noble

3. Proposed Classification
☐ None ☐ Restricted

4. Company/Product (Name)
BUSAN 1474

PM#
31

5. Name and Address of Applicant *(Include ZIP Code)*
Buckman Laboratories, Inc.
1256 N. McLean Blvd
Memphis, TN 38108
☐ *Check if this is a new address*

6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in repsonse to Agency letter dated _____
☐ "Me Too" Application.
☑ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

PRIA Category: ~~EPA No. A540~~, CR No. 476 - Action: New use, non-food, outdoor; FIFRA sec. 2(mm) uses
Reg. Fee: ~~$4,963~~
New Registration: BUSAN 1474 - End-Use-Product [Antimicrobial Product]
New Use for PC Code 5302
Contact: cfwatson@buckman.com; Fax (901) 272-6256

Typo to Mistake

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☑ No	☐ Yes ☑ No	☐ Yes ☑ No	☑ Metal ☑ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information
☐ Label ☑ Container

4. Size(s) Retail Container
5, 10, 15, 20, 30, 55 & 250 gal, Bulk

5. Location of Label Directions
☑ On Label

6. Manner in Which Label is Affixed to Product
☑ Lithograph / Paper glued / Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Carl Watson	Sr. Regulatory Toxicologist	(901) 272-6228

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature
Carl F Watson

3. Title
Sr. Regulatory Toxicologist

4. Typed Name
Carl F. Watson, Ph.D.

5. Date
30 September 2014

Kang, Ji Yeon

From: Carl Watson <cfwatson@buckman.com>
Sent: Wednesday, October 08, 2014 4:15 PM
To: Kang, Ji Yeon
Subject: RE: Submission to EPA: BUSAN 1474 (EPA Reg#1448-UUE)
Attachments: SKMBT_42314100813460.pdf

Joyce,

Please find attached signed copies of the revised Basic and Alternate CSFs for the submission, EPA File Symbol 1448-UUE.

Regards,

Carl F. Watson, Ph.D.
Sr. Regulatory Toxicologist

Buckman **North America**
1256 N. McLean Blvd
Memphis, TN 38108
901.272.6228 Office
901.272.6256 Fax
cfwatson@buckman.com

Commitment makes the best chemistry.

From: Kang, Ji Yeon [mailto:Kang.Joyce@epa.gov]
Sent: Wednesday, October 08, 2014 11:12 AM
To: Carl Watson
Cc: Ashe, Anthony; Clausen, Kirk; Cipicchio, Carleigh; Burkhart, Kira
Subject: RE: Submission to EPA: BUSAN 1474 (EPA Reg#1448-UUE)

Dear Mr. Watson,

My name is Joyce Kang and I am a contractor with the EPA. I am contacting you in regards to your submission in support of the product BUSAN 1474 (EPA Reg. No. 1448-UUE). We have found several deficiencies with the submission that will need to be addressed:

1. From CFS (Alternate Formulation), Ammonium Sulfate needs to be marked as Pre-Reaction and Ammonia as Post-Reaction as you confirmed by phone.
2. For BCMW, please write 100 % Re-Pack on the CSF (Basic Formulation).

Please send the revised CSF before Oct 16th, so that we may further process your submission. After Oct 16th, please direct all correspondence/corrections to the appropriate EPA Risk Manager. If you have any questions, please do not hesitate to contact me.

Best,

Joyce Kang

Contractor, US EPA
2777 S. Crystral Drive, S-4822
Arlington, VA 22202
(703) 347-0416
Email: kang.joyce@epa.gov

Kang, Ji Yeon

From: Carl Watson <cfwatson@buckman.com>
Sent: Wednesday, October 08, 2014 1:57 PM
To: Kang, Ji Yeon
Subject: RE: Submission to EPA: BUSAN 1474 (EPA Reg#1448-UUE)

Thanks,

Carl

From: Kang, Ji Yeon [mailto:Kang.Joyce@epa.gov]
Sent: Wednesday, October 08, 2014 11:57 AM
To: Carl Watson
Cc: Ashe, Anthony; Clausen, Kirk; Cipicchio, Carleigh; Burkhart, Kira
Subject: RE: Submission to EPA: BUSAN 1474 (EPA Reg#1448-UUE)

Good afternoon Mr. Watson,

Everything looks fine, and you can send me an electronic copy.

If you have any other questions, please do not hesitate to contact me.

Have a nice day,

From: Carl Watson [mailto:cfwatson@buckman.com]
Sent: Wednesday, October 08, 2014 12:48 PM
To: Kang, Ji Yeon
Subject: RE: Submission to EPA: BUSAN 1474 (EPA Reg#1448-UUE)

Joyce,

Before I submit these for signature, please confirm that the changes made to the two draft CSFs are acceptable per instructions. Also, once signed, does a paper copy need to be submitted, or can an electronic copy be sent to your attention?

Regards,

Carl F. Watson, Ph.D.
Sr. Regulotory Toxicologist

Buckman North America
1256 N. McLean Blvd
Memphis, TN 38108
901.272.6228 Office
901.272.6256 Fax
cfwatson@buckman.com

Commitment makes the best chemistry.

From: Kang, Ji Yeon [mailto:Kang.Joyce@epa.gov]
Sent: Wednesday, October 08, 2014 11:12 AM
To: Carl Watson
Cc: Ashe, Anthony; Clausen, Kirk; Cipicchio, Carleigh; Burkhart, Kira
Subject: RE: Submission to EPA: BUSAN 1474 (EPA Reg#1448-UUE)

Dear Mr. Watson,

My name is Joyce Kang and I am a contractor with the EPA. I am contacting you in regards to your submission in support of the product BUSAN 1474 (EPA Reg. No. 1448-UUE). We have found several deficiencies with the submission that will need to be addressed:

1. From CFS (Alternate Formulation), Ammonium Sulfate needs to be marked as Pre-Reaction and Ammonia as Post-Reaction as you confirmed by phone.
2. For BCMW, please write 100 % Re-Pack on the CSF (Basic Formulation).

Please send the revised CSF before Oct 16th, so that we may further process your submission. After Oct 16th, please direct all correspondence/corrections to the appropriate EPA Risk Manager. If you have any questions, please do not hesitate to contact me.

Best,

Joyce Kang

Contractor, US EPA
2777 S. Crystral Drive, S-4822
Arlington, VA 22202
(703) 347-0416
Email: kang.joyce@epa.gov

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to : Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: September 29, 2014	EPA Reg No./File Symbol 1448-___	Page 1 of 1
Applicant's/Registrant's Name & Address: Buckman Laboratories International, Inc. 1256 North McLean Blvd. Memphis, TN 38108	Product **BUSAN 1474**	

Ingredient: Ammonia, CASRN 7664-41-7; EPA PC #5302

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry Series 61	All Data Requirements	464351-02	Buckman Laboratories, Inc.	OWN	
Product Chemistry Series 62	All Data Requirements	464351-02	Buckman Laboratories, Inc.	OWN	
Product Chemistry Series 63	All Data Requirements	464700-02/ 465866-01	Buckman Laboratories, Inc.	OWN	
TOXICOLOGY					
870.1100 (81-1)	Acute Oral Toxicity – Rat	464351-08	Buckman Laboratories, Inc.	OWN	
870.1200 (81-2)	Acute Dermal Toxicity – Rabbit/Rat	464351-09	Buckman Laboratories, Inc.	OWN	
870.1300 (81-3)	Acute Inhalation Toxicity – Rat	464351-10	Buckman Laboratories, Inc.	OWN	
870.2400 (81-4)	Primary Eye irritation – Rabbit	464351-11	Buckman Laboratories, Inc.	OWN	
870.2500 (81-5)	Primary Dermal Irritation – Rabbit	464351-12	Buckman Laboratories, Inc.	OWN	
870.2600 (81-6)	Dermal Sensitization – Guinea Pig	464351-13	Buckman Laboratories, Inc.	OWN	

Signature Carl Watson	Name and Title Carl F. Watson, Ph.D., Sr. Reg. Toxicologist	Date 09/29/14

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to : Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: September 29, 2014	EPA Reg No./File Symbol 1448-___	Page 1 of 1
Applicant's/Registrant's Name & Address: Buckman Laboratories International, Inc. 1256 North McLean Blvd. Memphis, TN 38108	Product **BUSAN 1474**	

Ingredient: Ammonia, CASRN 7664-41-7; EPA PC #5302

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Buckman Laboratories, Inc.	OWN	
			Buckman Laboratories, Inc.	OWN	
			Buckman Laboratories, Inc.	OWN	
			Buckman Laboratories, Inc.	OWN	
			Buckman Laboratories, Inc.	OWN	
			Buckman Laboratories, Inc.	OWN	
			Buckman Laboratories, Inc.	OWN	
			Buckman Laboratories, Inc.	OWN	
			Buckman Laboratories, Inc.	OWN	

Signature	Name and Title	Date
Carl F. Watson	Carl F. Watson, Ph.D., Sr. Reg. Toxicologist	09/29/14

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Buckman Laboratories, Inc., 1256 N. McLean Blvd, Memphis, TN 38108 (901) 272-6228	EPA Registration Number/File Symbol 1448-_____ (New Registration)
Active Ingredient(s) and/or representative test compound(s) Ammonia (PC Code 5302, EPA Reg. No. 1448-432)	Date September 30, 2014
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Industrial, Aquatic, Outdoor, Non-food	Product Name BUSAN 1474

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
Carl F. Watson	09/30/14	Carl F. Watson, Ph D., Sr. Regulatory Toxicologist

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

QUESTIONS? (901) 272-6451

Buckman Laboratories Inc.
1256 North McLean Blvd.
Memphis TN 38108-1241

1056
*000 0008002 00000000 004 006 07220 INS: 0 0
US ENVIRONMENTAL PROTECTION AGENCY
FINANCIAL SERVICES DIVISION
P.O. BOX 360277
PITTSBURG, PA 15251

REFERENCE	INVOICE	GROSS AMOUNT	DEDUCTIONS	AMOUNT
NEW USE BSN 1474-A480	8/14/14 PRIA FEE	18234.00	0.00	18234.00

CHECK NUMBER	DATE	VENDOR NO.	NAME	TOTAL AMOUNT
0003007334	08/21/2014	210844	US ENVIRONMENTAL PROTECTION AGENCY	$18,234.00

CHOB1 v.4 10-27-11

ORIGINAL DOCUMENT IS PRINTED ON CHEMICAL REACTIVE PAPER WITH MICROPRINTED BORDER - DO NOT CASH IF THE WORD VOID IS VISIBLE

66-156/531

CHECK NO.
0003007334

DATE OF CHECK
08/21/2014

Buckman Laboratories Inc.
1256 North McLean Blvd.
Memphis TN 38108-1241

VOID AFTER 90 DAYS

PAY: EIGHTEEN THOUSAND TWO HUNDRED THIRTY FOUR AND 00/100 DOLLARS

CHECK AMOUNT
$18,234.00

TO THE ORDER OF US ENVIRONMENTAL PROTECTION AGENCY
FINANCIAL SERVICES DIVISION
P.O. BOX 360277
PITTSBURG PA 15251

AUTHORIZED SIGNATURE

Bank of America

AUTHORIZED SIGNATURE

DOCUMENT CONTAINS A TRUE WATERMARK - HOLD AT AN ANGLE TO SEE WATERMARK - CONTAINS REVERSE-BOARD PROTECTION FEATURES

⑈0003007334⑈ [redacted]

Commercial/financial information may be entitled to confidential treatment

31

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 10/1/14

Experts In-Processing Signature: MF Date 10/3/14 Fee Paid: Yes ✓

Division management contacted on issues No _____ Yes _____ Date _____

EPA Reg. Number: 1448-LLL	EPA Receipt Date: 10/1/14

	Items for Review			Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1) signed & complete including package type			X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A) No inerts in product	**yes**	**no**			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	**yes**	**no**			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	**Formulator's Exemption Statement** (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
5	**Data Matrix** (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
	a) Selective Method (Fee category experts use)	**yes** X	**no**			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	**5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)**			X		
7	**Is the data package consistent with PR Notice 86-5**					X
8	**Notice of Filing included with petitions**					X

9	**If applicable for conventional applications, <u>reduced risk rationale</u>**			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

* No studies submitted with application
* Called Submitter for active ingredient clarification on 10-1-14
* Submitter confirmed Ammonium Sulfate is pre-reaction 2 BCM to 100% re-pack. Will send new CSF. 10-8
* New CSF received on 10-9-14
* 100% repack no waste to review
* Jacket Passed

JA

MRID. None

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Ageney will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or

3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 3, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-495990
EPA File Symbol or Registration Number: 1448-UUE
Product Name: BUSAN 1474
EPA Receipt Date: 01-Oct-2014
EPA Company Number: 1448
Company Name: BUCKMAN LABORATORIES INC.

CARL F. WATSON, Ph.D.
BUCKMAN LABORATORIES INC.
1256 NORTH MCLEAN BLVD
MEMPHIS, TN 38108

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A480

NEW USE;NON-FOOD;OUTDOOR FIFRA SEC 2(MM) USES 1;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 347-0228.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{958589q~

This package includes the following

- (•) New Registration
- ( ) Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- (•) AD
- ( ) BPPD
- ( ) RD

Risk Mgr. 31

Receipt No. S- 958589

EPA File Symbol/Reg. No. 1448-UUE

Pin-Punch Date: 10/1/2014

☐ This item is NOT subject to FFS action.

Action Code:

Requested: A450

Granted: A450

Amount Due: $ 18,234

Parent/Child Decisions:

☐ Inert Cleared for Intended Use ☐ Uncleared Inert in Product

Reviewer: Team 4 Date: 10-2-2014

Remarks:

Confidential Statement of Formula may be entitled to confidential treatment